REMARKS/ARGUMENTS

As a result of this Amendment, claims 1, 2-11, 13, and 15-19 are under active consideration in the subject patent application.

In the Official Action, the Examiner has:

(1) acknowledged the Request for Continuing Examination, and withdrew the finality of the previous Office action;

(2) rejected claims 1-11, 13, and 15-19 under 35 U.S.C. § 103 (a) as being allegedly unpatentable over a proposed combination of U.S. Patent No. 6,370,511, issued to Dang, U.S. Patent No. 6,277,071, issued to Hennessy et al., U.S. Patent No. 6,077,082, issued to Gibson et al., when further combined with a publication entitled "Closed Dressings After Skin Resurfacing," by James P. Newman, R. James Koch, Richard L. Goode, *Archives Of Otolaryngology – Head & Neck Surgery*; Chicago,: July 1998. Vol. 124, Issue 7; Pgs. 751-758 (the "James" reference);

(3) identified prior art made of record and not relied upon but considered pertinent to Applicant's disclosure; and

(4) attached an interview summary of a telephonic interview between Examiner, Applicant's attorney and Supervisor Joseph Thomas on June 30, 2004, in which claims 1, 11 and 17 were discussed.

With regard to Item 1, no comment appears to be necessary.

With regard to Item 2, Applicant respectfully traverses the Examiner's proposed combination of the Dang, Hennessy and Gibson references with the disclosure of the James reference, and requests reconsideration and withdrawal of the rejection of claims 1-11, 13, and 15-19, as amended, under 35 U.S.C. §103 for the following reasons.

The primary objective of the present invention is to provide a process for accessing and documenting wound and skin conditions that includes an automatically triggered alerting mechanism that is activated, in real time, when a treatment, at the time of performance of a clinical action, is initiated on a living, breathing patient by a treating physician, which treatment deviates from an expected or standard treatment under the then current clinical circumstances. Applicant's method begins with gathering patient care data by applying a risk assessment tool to a patient comprising a rating scale (e.g., a Braden Scale) to objectively characterize the subjective condition of that patient's skin and wound thereby diagnosing a malady in real time and at the bedside of the patient. Moreover, none of the foregoing references relied upon by the Examiner suggest use of a decision guide that provides a plurality of descriptors for use in objectively characterizing the subjective condition of a patient's skin and wound. Each of independent claims 1, 9, 15, 17, 18, and 19 have been amended so as to more particularly and distinctly claim these features of Applicant's invention. Support for these changes to the claims may be found in the specification at, e.g., pages 11-12, 13-14, and 16, in the drawings, and at least in original claim 2.

Neither Dang, Hennessy, Gibson nor James references alone or in any valid combination provide or suggest such a methodology, and neither provide the requisite motivation to combine them as the Examiner has done, absent impermissible hindsight.

The Examiner has admitted that Dang, Hennessy, or Gibson references do not collectively disclose the limitation "wherein said clinical action includes implemented a skin and wound care regimen comprising selection and application of dressings to a wound; monitoring and comparing said recorded clinical actions taken by said clinician, at the time of performance of said clinical action." Moreover, none of these references taken alone or, in any valid combination with one another or with the James reference, teaches or suggests that patient care data be gathered directly from a patient by applying a risk assessment tool to the patient that comprises a rating scale to objectively characterize the subjective condition of that patient's skin or wound.

At page 4 of the Official Action, the Examiner mischaracterizes the Hennessy reference when referring to Fig. 20 and col. 10, lines 29-60, inasmuch as Hennessy does not teach or suggest gathering patient care data by applying a risk assessment tool of any kind to a patient, let alone one that provides a rating scale or the use of a decision guide that provides a plurality of descriptors. Instead, at col. 10, lines 29-60, Hennessy teaches as follows:

> ". . .Referring to FIG. 15, an example of the type of report which may be generated as a result of the chronic disease monitor 10 is illustrated. It will be appreciated to those of ordinary skill in the art, that by applying the guideline and logic sequence described herein,

> that various reports may be generated to assist the physician, patient, and/or pay provider to monitoring the chronic disease. The user, via user terminal 18, selects the menu setting forth the provider record 30, which associates information with respect to a medical provider such as a physician. For the physician, the alerts are categorized by patient, date, test type, detail (goal, threshold, result). Reminders are also listed for the respective physician, indicating the date created, schedule, patient name, author and the subject. As illustrated in FIG. 16, the patient population may be viewed globally, setting forth the number of patients seen by the provider, the test frequency, test results, with graphical illustrations. Quality reports for patients, setting forth the patient population, including the category of diabetes, the number of patients and percentage of the patient population, the tests undertaken on the patient population, and the average result of those tests, are illustrated in FIG. 17. As shown in FIG. 18, a high risk patient list can be generated for distribution to providers, payers, etc. The background criteria is stored behind each high risk patient in window format. As illustrated in FIG. 19, a quality report by provider, setting forth the category, patients, percentage of patients by diabetes type, test (eye exam, foot exam, lipids, etc.) may be accessed.
>
> As shown in FIG. 20, additional information, such as warning signs concerning symptoms and signs of foot disease may be stored (and optionally communicated to the patient). . . ."

It should be further noted that FIG. 20 of Hennessy merely associates one subjective characterization of a skin malady to another subjective characterization of a skin malady, e.g., *painful* wound - *abnormal* dryness. No risk assessment tool comprising a rating scale (e.g., a Braden Scale) or the use of a decision guide that provides a plurality of descriptors is suggested or taught that would allow a clinician to objectively characterize a subjective condition of the skin or a wound. Hennessy instead teaches the use of a retrospective report that is created after performance of clinical actions as a review of patient

information, i.e., a report is provided to "*the physician, patient, and/or pay provider to monitoring the chronic disease.*" *[sic]* This information is provided well after any clinical activity has taken place, and not at the time of performance of a clinical action identified as a variance so as to allow a clinician to alter the clinical action.

Moreover, there is simply no teaching of applying a risk assessment tool to a patient comprising a rating scale or the use of a decision guide that provides a plurality of descriptors to objectively characterize the subjective condition of the patient's skin and wound thereby diagnosing a malady. This shouldn't be surprising, since Hennessy, Dang, and Gibson are not directed to real time patient assessment and care methodologies - as acknowledged by the Examiner in admitting that claims 1-11, 13, and 15-19, are patentable over the combined teachings of Dang, Hennessy and Gibson (page 3, last two lines of the Official Action).

The Examiner states that the limitations relating to clinical action that include implementing a skin and wound care regimen comprising selection and application of dressings to a wound, and monitoring and comparing recorded clinical actions taken by a clinician, at the time of performance of said clinical action are taught by the James reference. However, James fails to teach or suggest applying a risk assessment tool to a patient comprising a rating scale to objectively characterize the subjective condition of that patient's skin and wound thereby diagnosing a malady which would then trigger the selection and

application of dressings. Instead, James is directed to post operative care of a patient after laser surgery. James does not concern itself with providing a process for accessing and documenting skin condition after laser surgery, nor does James et al., suggest at page 3, paragraphs 2-6 or page 5, paragraphs 1-3 gathering patient care data by applying a risk assessment tool to a patient comprising a rating scale or using a decision guide that provides a plurality of descriptors to objectively characterize the subjective condition of that patient's skin and wound.

Accordingly, the proposed combination of Hennessey, Dang, and Gibson with the disclosure of James fails to teach or suggest the methodologies and systems defined by claims 1, 2-11, 13, and 15-19.

Reconsideration and withdrawal of the rejection of claims 1, 2-11, 13, and 15-19, under 35 U.S.C. §103 are respectfully requested.

With regard to Item 3, Applicants have considered the prior art references identified by the Examiner as pertinent and determined that the none of them, taken alone, or in any valid combination with the Hennessey et al., Dang, Gibson et al., or James references anticipates or renders obvious the present invention.

Since nothing in the prior art references relied upon to date by the Examiner would lead a person of ordinary skill in the art to provide a methodology like that described in the application, or defined by claims 1, 2-11, 13, and 15-19, it appears that hindsight knowledge of the present invention would be the only motivation to combine these references. The Examiner is reminded

that it is improper to use the claims as a framework with individual parts of separate prior art references employed to recreate a facsimile of the claimed invention. See, *W. L. Gore and Associates, Inc. v. Garlock, Inc.* 220 U.S.P.Q. 303, 312.

In summary, Applicant submits that the unique methodology defined by claims 1, 2-11, 13, and 15-19 is not disclosed in the cited prior art references, taken as a whole, and there is no teaching or suggestion in the references to support their use in the particular claimed combinations. In the absence of such, the references are improperly combined. In any event, claims 1, 2-11, 13, and 15-19 define over the various proposed combinations of Dang, Hennessy, Gibson and James .

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Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

If a telephone conference would be of assistance in advancing prosecution of the above-identified application, Applicant's undersigned Attorney invites the Examiner to telephone him at **717-237-5516**.

Respectfully Submitted,

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